

Intellectual Property REPORT

University of Oxford iGEM Team 2014



A report into the intellectual property aspect of the iGEM competition and its implications for students, particularly those who may wish to develop their project beyond iGEM. This report is not intended to be nor does it purport to be legal advice, and should not be relied on without consulting a qualified professional.



“If a true modern bioeconomy is to emerge in the years ahead, intellectual property will no doubt play a critical role. Intellectual property rights – the manner in which they are recognised, traded, and managed, nationally as well as globally – will influence the form such a bioeconomy takes, where it will flourish and flounder, and to whom the principal benefits will flow...”

(Matthew Herder and E. Richard Gold)¹

Introduction...

Dr Jonas Salk, who invented the polio vaccine in the 1950s, was once asked why nobody owned the patent on it. "Why?" he replied,

"Could you patent the sun?"

iGEM, like all areas of synthetic biology, has had to develop an intellectual property policy. Currently this policy requires that all Biobricks submitted are donated to the public domain by signing the Biobrick agreement². The sharing of intellectual property through the Biobrick agreement has brought many advantages, and has undoubtedly contributed to the rapid rate of progress in synthetic biology in recent years....

However, the Biobrick agreement, as the name suggests, is only relevant to Biobricks. What of the rest of the intellectual property an iGEM team may create during the course of their project?

Currently, the situation appears to be that anything other than a Biobrick may be the subject of a patent. Indeed, one of iGEM's greatest achievements as an institution is the number of start-up companies which it has fostered³, many based on a continuation of the project they began for the competition. Even more projects have the potential to be turned into such an enterprise or to attract investment from other sources. In order to enable this to happen, it is necessary that IP rights relating to the project be protected in some form – without them, investment in a team's idea is highly unlikely to be commercially viable as there is nothing to stop competitors from taking advantage of the idea.

The problem encountered here is the fundamental struggle of intellectual property law: **how can the law balance openness with investment?**

The Law...

What is Intellectual Property?

Intellectual Property is the main area of law regulating expressive, informational, and technological subject matter. It serves three primary purposes:

- **Promoting innovation and creativity**

For example, this area of law is essential to pursuing the solutions to environmental and health problems, and securing the future of ideals such as freedom of expression and democracy.

- **Stimulating economic growth and competition**

- **Enabling business**

‘Every year in the last decade, investment by UK business in intangible assets has outstripped investment in tangible assets: by £137 billion to £104 billion in 2008. Global trade in IP licences alone is worth £600 billion a year: 5% of world trade and rising’⁴.

In the competitive global market, patenting is the key to enormous profitability. Pharmaceuticals have been rated either first or second in the Fortune 500 list of most profitable sectors for 30 of the past 40 years.

How does this apply to synthetic biology?

Synthetic Biology must decide whether, and how, it wishes to protect intellectual property. This is a decision which will shape the future of the field in every possible way. It will determine the primary sources of funding and the extent of investment in the science, which in turn will have an influence over the nature of the research undertaken and the uses to which discoveries are applied. The role of synthetic biology in society will be determined largely by the ownership of intellectual property.

The BioBrick Agreement

The BioBrick Public Agreement is a legal tool employed by many synthetic biologists including those taking part in iGEM to share intellectual property. Contributors add parts to the ‘Bank’ of parts which are then freely available to researchers who wish to use them. Read a preview of the contributor agreement [here](#) and a full version of the user agreement [here](#).

There’s no denying that intellectual property is a controversial issue...

THE WALL STREET JOURNAL.

Generic OxyContin Pains the FDA

Patent Expiration
Brings Debate Over
Abuse Deterrents

Illustration by M...

The Washington Post

Patent office filters report on abuses

PATENT FROM AB...

...a lot less emotional. The true
extent of the problem is not...

But these examples - and others
listed in the internal report -
did not appear in the damage
survey to Zomer. That tension
supplied to Zomer. That tension...

THE WORLD
THE COMPUTER COMMUNITY

June 18, 2013

First Patent Is Issued for Software, Full Implications Are Not Yet Known

By MICHAEL WATSON, JR., The
Wall Street Journal

Details of first patent are
set to be filed in U.S.

Microsoft's first patent is a
complete patent covering a
software program that uses a
new data structure to search a
large database for information.

April 25, 2013

U.S. PATENT

U.S. PATENT

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Angelina Jolie, corporate patents on genes, and the U.S. Supreme Court

Thursday, May 16, 2013

by Mike Adams, the Health Ranger
Editor of NaturalNews.com (See all articles...)
Topic: Angelina Jolie, gene patents, Supreme Court

Pest and vermin...

FREE OUR GENES!

It's
about
A GEN-A
Mutation

It's
about
GEN-A
Mutation

Weighing the Rights of the Embryo Against

What Only the Embryo Knows

By JAMES L. MCGEE
The embryo is a creature of great potential, but it is also a creature of great mystery. It is the only creature that can be created from a single cell, and it is the only creature that can be destroyed. It is the only creature that can be used for research, and it is the only creature that can be used for therapy. It is the only creature that can be used for both, and it is the only creature that can be used for neither.

NIH Pulls Plug on Ethics Review

Advocates for research with human embryos are disappointed that the National Institutes of Health (NIH) has decided to pull the plug on its ethics review process. The NIH had been planning to launch a new ethics review process for research involving human embryos, but it has now decided to scrap the plan. This decision is seen as a major setback for those who support research with human embryos.

Patents are a virtue

14 Apr 2002 | Finance

WE live in the information age, and intellectual property (IP) rights are rapidly replacing hard assets as the greatest store of commercial value. Patents, copyrights and trademarks are frequently worth more than factories, machines or stock...

Apple awarded 'sexting' patent

13 Oct 2010 | Claudine Beaumont | Technology



The patent, which was filed by Apple in 2008, concerns "systems, devices and methods" for filtering "text-based messages" that contain "objectionable content..."

Cost of defending patents capped

27 Sept 2010 | Finance



Inventors receive a boost this week when the cost of defending intellectual property claims in the county courts is capped for the first time. Individuals and small businesses that use the Patent County Court to defend their patents, trademarks or copyrighted materials against infringement from October 1 only face costs of up to £50,000 if they lose...

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HOME > CULTURE

Patent greed

In search of a more ethical pharmaceutical industry

12:00AM BST 21 Apr 2011

Comment

DR JONAS SALK, who invented the polio vaccine in the 1950s, was once asked why nobody owned the patent on it. "Why?" he replied. "Could you patent the sun?" Sadly, the pharmaceutical industry does not abide by such a philosophy. In the competitive global market, patenting is the key to enormous profitability. Pharmaceuticals have been rated either first or second in the Fortune 500 list of most profitable sectors for 30 of the past

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The Problem...

The mission of synthetic biology goes far beyond traditional recombinant DNA technology – the subject aims to make biology a ‘true engineering discipline’, using standard molecular genetic ‘parts’ which can be synthesised and combined in different ways. MIT’s registry of standard biological parts which ‘records and indexes biological parts currently being built and offering synthesis and assembly services to construct new parts, devices, and systems’⁵.

Synthetic Biology occupies the junction between biotechnology, electronics, software, and information technology – it therefore poses a novel challenge in terms of intellectual property law. Patents of basic parts and devices present a high risk of delaying the development of the science due to prohibitively high transaction costs.

On the other hand, there is disagreement regarding different methods of procuring ‘openness’. Should certain types of property remain in the ‘public domain’, i.e. altogether outside the scope of intellectual property? Should intellectual property rules be used to create a ‘commons’ along similar lines to the development of software (creators of open source software use their IP rights as leverage to impose requirements of openness on programmers building on their work)? Many open source ideals and mechanisms require intellectual property rights to ensure that anyone using/developing the idea is bound by the licence terms the original creator wishes to impose. The boundaries between intellectual property and the public domain are not always clear cut.

Rich/poor divide - Developing countries are even re-framing their native genomic biodiversity as a natural resource, and staking their claim to it. Risk that IP rights could perpetuate inequalities – on the other hand example of Pfizer, profitable enterprises can be used to fund charitable activities e.g. developing treatment for tropical diseases.

Moreover, there is great concern that wrong decisions in this area could deepen the existing divide between rich and poor nations.

The Options...

Three potential policies which iGEM could choose to adopt are explored, along with the benefits and disadvantages of each are discussed below.

The Status Quo

Currently iGEM teams donate their intellectual property to the public domain using the BioBrick agreement. Contribution to this bank of 'parts' is a central part of the competition: a Bronze medal award requires teams to document a BioBrick; the Silver medal requires experimental validation, documentation, and submission to the registry of at least one new BioBrick developed by the team; to achieve a Gold award a team must improve the function or characterisation of an existing BioBrick.

The BioBrick Foundation (BBF) believes that '*fundamental biotechnology belongs to all of us*', but note that '*there are few tools to help people share this technology freely*'.

The BBF describes the BPA as a 'free to use legal tool that lets you make your standardised biological parts free for others to use'. It can be used to share any genetically encoded function which the contributor owns or makes anew. It operates as a contract between the contributor, the party wishing to make a genetically encoded function free to use, and a user who wishes to use it freely. By the agreement, the contributor makes an irrevocable guarantee not to assert intellectual property rights, meanwhile the user promises to provide attribution to the contribution and to respect biological safety practices and laws.

The BioBrick foundation states that '*donation to the public domain will speed the invention of lower cost synbio solutions while fostering ethical use of technology*'. The BioBrick agreement is a simple, hassle-free means of sharing ideas; the wider the pool of people with access to ideas, the more innovation and development of these ideas is likely to occur and ultimately the more progress can be made. The iGEM competition raises the profile of this resource, adds to the bank of ideas available, and reinforces the ideology of the BioBrick foundation. Other researchers can use the ideas contributed by iGEM teams to the registry and build on these to develop more useful ideas and products. Further, because the agreements are so straight-forward and self-explanatory – not a claim which could be made for many features of IP law! – participants of the competition do not need to waste time and energy thinking too deeply about intellectual property issues and do not need to spend money obtaining expensive legal advice. Because there is no 'give-back' obligation, the registry is open to everyone, and people should not be deterred from using material from it due to concerns about the ownership of any ideas which arise from their research using registry material. Finally, a good balance is struck between preserving open source principles, and maintaining the possibility of securing a patent in relation to applications and combinations of BioBricks.

On the other hand, in practice the lack of confidentiality makes it extremely difficult to secure patents in practice – witness the need for teams such as Calgary iGEM (discussed below) to protect their ideas using trade secret practices, which ultimately is more detrimental to open source ideals than is patent. Further, the BioBrick agreement only addresses intellectual property issues in relation to BioBricks – many questions remain to be answered in relation to other ideas and inventions which may arise in the course of an iGEM project. On these issues, there is a lack of understanding and accessible advice for iGEM teams.

The tables below summarise the main features, pros, and cons of a number of different policies open to iGEM in relation to IP issues.

The Status Quo

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| Pros | Cons |
|---|---|
| ✓ Sharing of ideas | ✗ Unclear situation regarding elements of the project which are not BioBricks |
| ✓ Simple legal formula, meaning participants don't have to spend time and energy thinking about intellectual property or waste money seeking advice | ✗ Lack of understanding amongst participants |
| ✓ No 'give-back' obligation | ✗ Difficulty obtaining advice/lack of education on legal issues for participants |
| ✓ Enables the competition to make a massive contribution to the field of synthetic biology which can be used by other researchers to develop useful products. | ✗ Lack of confidentiality makes it extremely difficult to secure patents in practice (because too much information is released to the public domain during the course of the competition and jamboree). |

Complete openness

Openness

This would involve excluding the option of securing IP protection in theory as well as in practice, preventing teams from applying for protection for any intellectual property developed during the course of the competition. All ideas would be in the public domain by virtue of being a part of iGEM. De facto this would make only minimal difference to the team's options as the disclosure requirements for the jamboree mean that obtaining protection is highly difficult – however, as a policy decision, this would be a highly significant step for iGEM to take.

| Pros | Cons |
|--|---|
| ✓ Sharing of ideas and increased availability of information in public domain | ✗ Teams may find it more difficult to secure funding to develop their projects after the jamboree |
| ✓ Very clear policy – no potential for confusion or misunderstanding | ✗ Start-ups springing from iGEM would become highly difficult and may become reliant on donations |
| ✓ No risk that worries about IP will distract teams from the competition or from their project | ✗ It may be detrimental to the public interest if a project with the potential to have a great positive social impact remained unexplored and undeveloped due to difficulties obtaining funding in the absence of IP rights to protect investors. |
| ✓ Encourages and supports the ethos of sharing enabled by the BioBrick agreement, without limiting this strictly to 'BioBricks' – this option would offer consistency of approach between BioBricks and other project elements | ✗ Risk that teams with genuinely great ideas might be reluctant to enter them to the public domain and by extension the iGEM competition, ultimately causing the competition to lose out |

Confidentiality

Confidentiality

Involves adding a confidentiality clause to the signup agreement for iGEM so that the jamboree and any collaboration or disclosure of information which takes place within the competition would no longer be in the public domain. One option would be to have a 'grace period' of a few weeks or so following the jamboree for teams to decide whether they wished to take any action to protect their intellectual property or for potential investors to express their interest, after which period the confidentiality clause would lapse and all information would become freely available in the public domain. Whilst parts would still be donated to the BioBrick™ registry, this would enhance the ability of teams to submit patent applications during the course of their project and in the run up to the jamboree.

| Pros | Cons |
|--|--|
| ✓ Teams could be completely open within iGEM and could be uninhibited by any IP concerns as to what they published or shared with each other | ✗ Organisational difficulties associated with implementing a confidentiality agreement in practice |
| ✓ The possibility of filing a patent at a later date would be preserved | ✗ Potential problems relating to public availability of information on wiki |
| ✓ All the advantages of the 'status quo' arrangement would effectively be maintained | ✗ Extra responsibility on competitors and judges to respect teams' intellectual property until after the lapse of the clause |
| ✓ The role of the BioBrick™ agreement could be preserved in compatibility with confidentiality | ✗ Difficult for students to know how much information they can release to other parties (e.g. sponsors, universities etc) without compromising their confidentiality. This will depend on individual circumstances |

Reach-Through License Agreement

Reach Through Licence Agreement

This is a useful application of existing contract law whereby a researcher need pay little or nothing (upfront) for access to parts in the registry developed by other contributors. However, if their research results in development of a marketed product, the contributor of the material originally used is entitled to a cut of the profits. This system offers much greater incentives than the current terms of the BioBrick™ Public Agreement. An RTLA may be able to offer the best of both worlds in balancing open source principles with investment interests.

| Pros | Cons |
|---|---|
| <ul style="list-style-type: none"> ✓ The open source principles of the registry could be maintained and researchers would continue to have the ability to carry out their work without worrying about intellectual property or economics – a result which would likely enrich the number and quality of scientific discoveries | <ul style="list-style-type: none"> ✗ The number of interested parties may make it difficult for a negotiated agreement to be reached in relation to revenues |
| <ul style="list-style-type: none"> ✓ The RTLA provides a strong incentive for industry to fund discoveries as product development comes at a very small cost (not having to purchase the intellectual property outright). Small and medium sized companies would benefit greatly from this development. | <ul style="list-style-type: none"> ✗ There is some concern that RTLAs may sap profits from small start-up companies (although in practice this is unlikely to be the case as such companies can in effect 'auction' to researchers the work it requires where it would lack the resources (financial or expertise) to perform this itself) |
| <ul style="list-style-type: none"> ✓ Any complications relating to the agreement would be the responsibility of companies wishing to profit from discoveries, meaning scientists need not be distracted with concerns about legal issues and profits | <ul style="list-style-type: none"> ✗ Complications of incorporating an extra clause into the agreement |
| <ul style="list-style-type: none"> ✓ As the intellectual property will remain available to a huge number of researchers, there is an increased potential to discover unforeseen applications and possibilities. | <ul style="list-style-type: none"> ✗ Any clause introduced would be applicable only to future rather than to existing BioBricks™ (those who had donated or used parts under the existing terms could not be compelled to agree retrospectively to an RTLA) |

Opinions...

Industry

We approached iGEM start-ups to ask what difficulties they had encountered when navigating the murky world of IP law following their success in the competition.

One thing we found was that most of the successful start-ups were primarily software based businesses. Generally we found they were more than happy to be contacted by a current iGEM team, interested in what we had to say, and eager to help us in any way they could. The feedback and experience offered by these companies and individuals is summarised below.

Morph Bioinformatics

Freedanz, on behalf of Morph Bioinformatics, was keen to share the company's experiences and views. Although as he pointed out software companies frequently have less cause to address IP issues at the moment (as algorithms and computer code currently cannot be patented).

Nevertheless, the company felt that the issue was important and relevant to them on a higher level. "For us the IP question is part of the most crucial question we, the iGEM community, have to find a[n] answer to: *How do we find the balance between following the 'open source' policy but adapting to the corporate reality?*"

One example mentioned by Morph was DIY: Freedanz felt that although undoubtedly it is 'great and necessary' to involve the public and show them the potential of synthetic biology, in order to adapt to the FDA regulations and commercial environment limits it is necessary for this to be confined to the appropriate context. His comments demonstrate that new start-ups are increasingly in touch with public perceptions and concerns as this

It was stressed that *"it is important to not apply 'black and white' thinking to this topic and force a debate between 'the public and the corporates'"*. It must be accepted that commercialization is crucial to translate innovation into something useful for society - playing around in the lab might be fun but it does not help anyone per se if you do not take the next step. On the other hand, the company recognised that aspects of open innovation – particularly sharing BioBricks – increase the productivity of research and development in biotechnology and pharmaceutical companies, and that this was something Morph themselves were keen to contribute to.

Therefore, Morph's view is that *"iGEM must position itself and not only define its role in the world of biotech - but also how it sees the role of synbio"*. iGEM's approach to intellectual property will be intrinsically related to its overall policy. *"It is time now to rationalize this 'big picture' and find a business model by treating the public, academia, biotech, pharma etc. as different units to optimize and synergize their outputs. And as with all business and communities the major factor of success is to follow one ultimate vision - and that should remain increasing the quality of life"*.

In terms of the iGEM competition, Morph would appear to support the introduction of non-disclosure agreement which would prevent anyone other than the creator of an idea/BioBrick from commercialising it and mean that the Jamboree would no longer be a public domain. *"By doing that*

patenting will not be a problem - and iGEM can keep on supporting the crucial movement of open source innovation without impeding the required corporate translation of the ideas".

Amplino

Amplino is a company developed based on an idea which began as a project in the iGEM competition. The company strongly expressed the view that intellectual property has little if any place in the iGEM competition and would discourage teams from promoting patenting and pursuing strategies towards

protection of intellectual property. *"In our opinion part of the iGEM challenge is to develop business models that work well with open source and public technology"*. iGEM should be about openness and contribution to public sharing of knowledge and a commons of information.

Pieter of Amplino outlined the general vision which Amplino supported thus: *"Let's try and build a future in which start-up companies no longer get harassed by patent trolls and waste their resource on pointless legal issues"*.

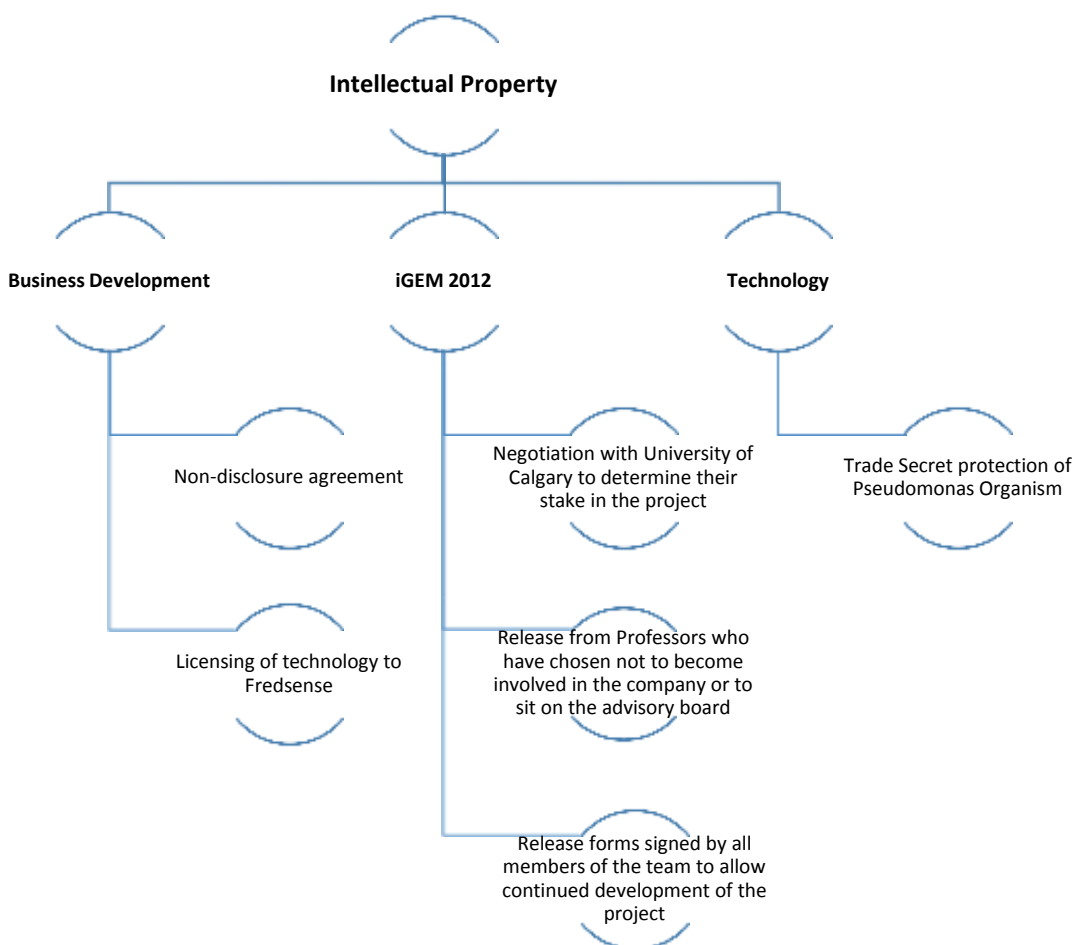
Fred Sense

The FredSense technology platform now being commercialised originated as a project of the Calgary iGEM team in 2012. 'This produced a unique intellectual property situation, as the technology came out of a collective project...[and] all of the work was disclosed publically'. As explored in the first

section of this report, confidentiality is generally a crucial requirement for securing intellectual property protection.

The approach to IP protection taken by Fredsense is summarised by the diagram on the left. Fredsense describe their experiences of approaching IP protection as a former iGEM project as 'uniquely challenging' and note that 'due to the increasing ease of genetic manipulation, it could be easy for competitive parties to copy and modify our system in the future'.

They explore other means of protecting IP, including use of kill switch technology and other genetic mechanisms



which make it difficult for the organism to be identified.

'The protection [of key components of the technology] is key to ensure the development and commercialisation of the technology' – to this end, the group has filed a provisional patent. Their experiences highlight the difficulties of reconciling an open source culture with commercialisation - but also a clear demonstration that with a little thought and imagination this can be done.

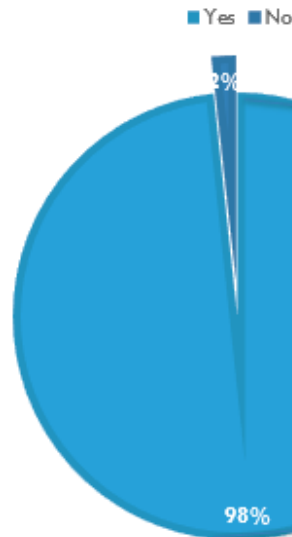
Students

We delivered a survey to iGEM teams across the world and extremely grateful for the high rate of responses. The results are illustrated and analysed below.

Statistical analysis

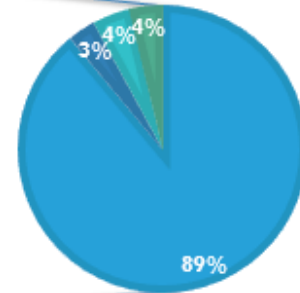
On the following pages is an analysis and graphic representation of the results of the IP survey we handed out to iGEM students.

DO YOU HAVE ANY EXPERIENCE OF INTELLECTUAL PROPERTY ISSUES PRIOR TO YOUR INVOLVEMENT IN iGEM?



DESCRIPTION OF EXPERIENCE

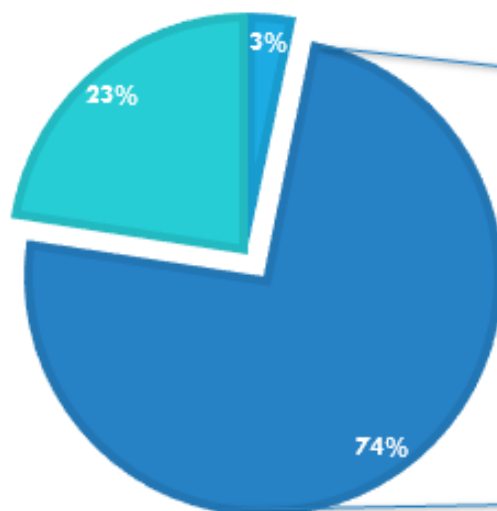
- I considered patenting/wanted to patent my idea, but didn't
- I patented my idea
- I used material patented by other people and/or wanted to ensure the material I used hadn't been patented
- Other (I considered using patented material but didn't)



The above graph confirms our suspicions based on the experiences (or rather lack thereof) within our own team, and also reaffirms the results of previous surveys by iGEM teams in past years². Given the broad range of experiences suggested, we suggest that many people have had some experience of patent, for example using or considering using patented material, without realising it. The remarkably low proportion of iGEMmers who have no experience of IP issues prior to entering the competition confirms the need for advice/guidance to be given to team members. The chart above shows that lack of information is a primary reason for teams not patenting their ideas reinforces this impression.

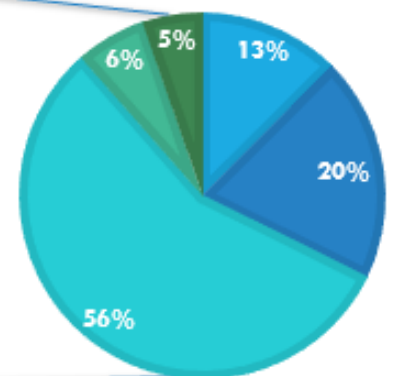
HAS YOUR TEAM CONSIDERED APPLYING FOR IP RIGHTS TO YOUR CURRENT PROJECT?

- Application made ■ Considered but decided against ■ Did not consider

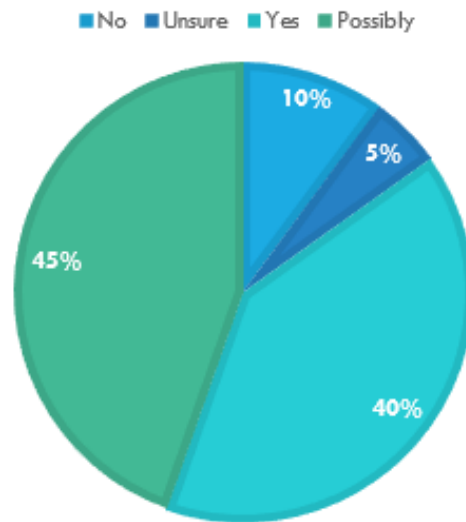


REASON(S)

- Time/Effort involved
- Expense involved
- Lack of information/understanding
- Moral/Ethical reasons
- Other



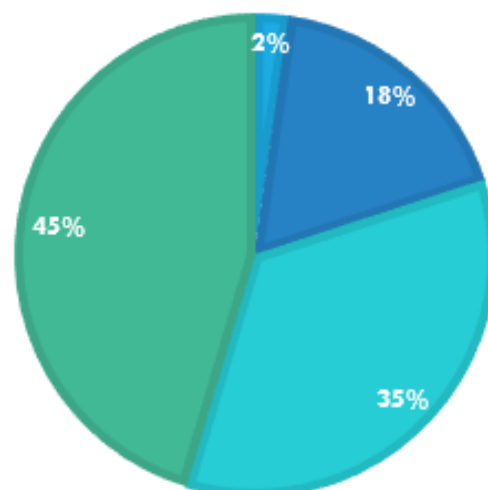
DO YOU BELIEVE YOUR PROJECT HAS THE POTENTIAL TO BE PROFITABLE COMMERCIAL/MAY ATTRACT INVESTMENT?



The majority of teams (85%) appear to feel that there is at least the possibility that their project could be turned into a viable business or project – this makes sense given that many teams seek to use their project as an opportunity to use synthetic biology to address a problem. It follows from this that the students naturally believe there is a market and demand for their project. This result is also supported by the number of successful iGEM start-ups³. It's fantastically empowering and gives a real sense of achievement to believe that your project could have an impact on the real world in this way!

WHICH OPTION DO YOU BELIEVE WOULD BE ALLOW YOUR PROJECT TO BE DEVELOPED TO BRING THE MAXIMUM BENEFIT TO SOCIETY?

■ Realistically unlikely to bring benefit to society ■ Public sector investment ■ Donation to the public domain ■ Commercial Investment



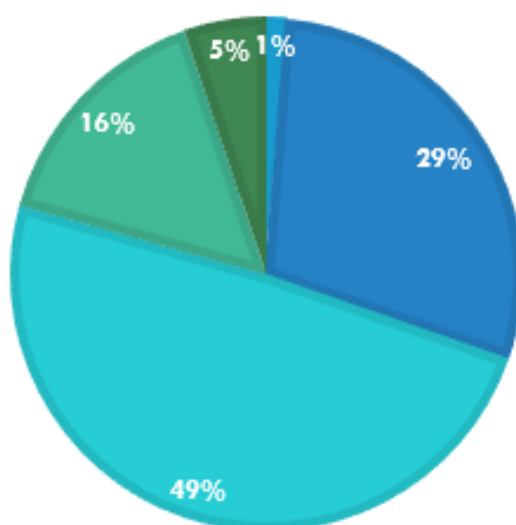
Again this chart shows how few teams believe their project is relevant to society. There was a split, slightly skewed towards commercial investment, in terms of the favoured means of funding, although it should be noted that many participants selected more than one option, suggesting mixed feelings and uncertainty on this question. Some of the participants who were also interviewed commented that

although public sector investment was an ideal source of funding, in reality this was not and could not be available on the scale necessary to support all new up and coming projects. The main drawbacks of commercial funding were that students were cautious of the commercialisation of their ideas and particularly the possibility that they would lose control over their development and that benefit to society might be sacrificed in the interests of profit for the relevant company.

Donation to the public domain was a popular option, indicating that many students support the BioBrick agreement and are keen to contribute their parts to it, moreover that this is the best way to achieve progress in synthetic biology. However, some of those who did not select this option expressed concerns that without proper regulation their ideas may be abused, for example in DIY home laboratories, and turned to purposes they were not intended for which would be detrimental to society. Although regulatory difficulties would make it hard for inventors to enforce their IP rights at an early stage to stop them being used for research and development purposes which they were not happy with, it is likely that these uses would come to light before any such abusive invention was put to use – possession of IP rights would enhance the original inventor's ability to put a stop to any abuses at this stage.

HOW WOULD YOU DESCRIBE YOUR UNDERSTANDING OF THE INTELLECTUAL PROPERTY ISSUES RELEVANT TO SYNTHETIC BIOLOGY?

■ Thorough ■ Adequate ■ Vague ■ Non-Existence ■ Disinterested

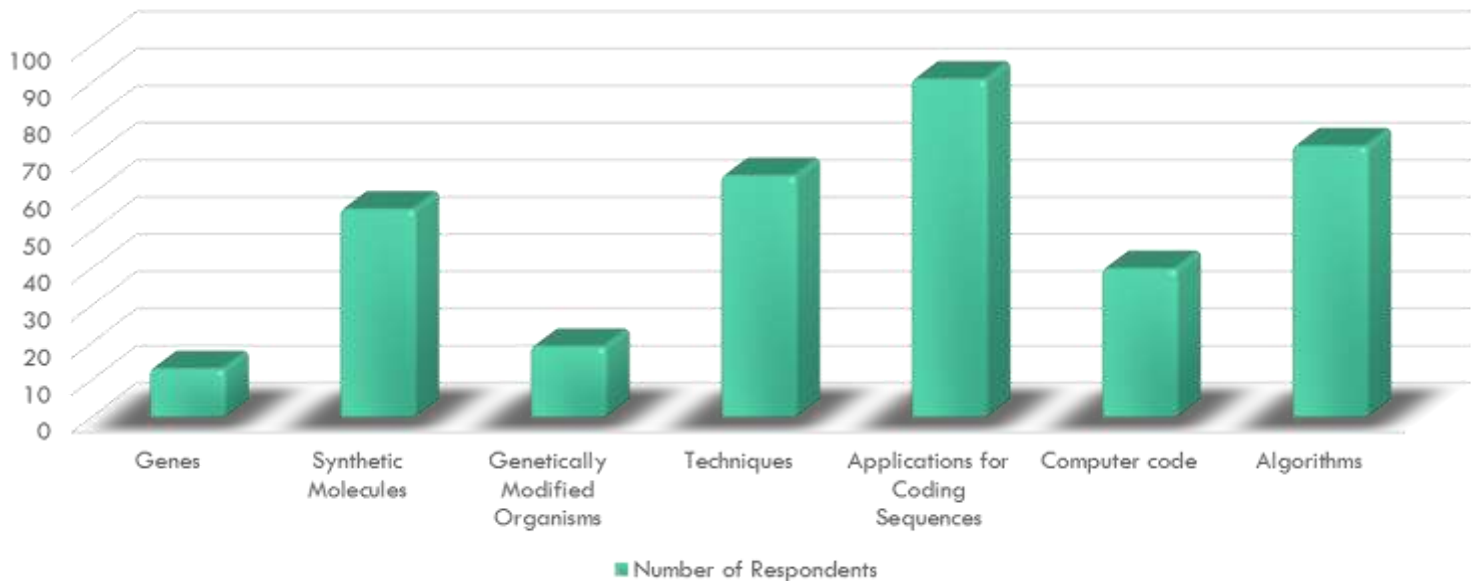


Again, responses to this question support the need for guidance for iGEM teams on IP issues. We were slightly surprised to see 29% of the respondents felt that their current level of understanding was 'adequate'. Possible explanations for this include: evidence of a Dunning-Kruger effect whereby people overestimate their level of knowledge, often because their level of understanding is such that they 'don't know what they don't know'; underestimating the significance and relevance of intellectual property law to synthetic biology (and consequently believing that a low level of understanding will suffice); or a genuinely adequate understanding amongst students.

The number of respondents believing their IP knowledge to be 'non-existent' (16%) suggests, as before, that students are not necessarily aware of when they are coming across IP rights. It is highly unlikely (especially given that these 16% of respondents had sufficient awareness to answer the rest of the questions without difficulty) that these students had no knowledge whatsoever regarding IP law and its relevance for synthetic biology.

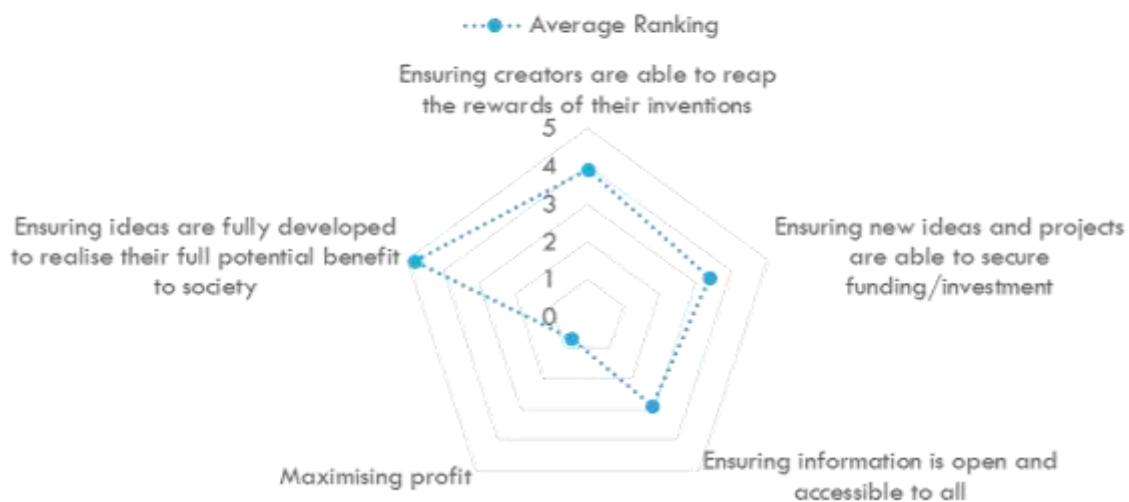
The graph below shows the views of students as to what is and is not appropriate subject matter for a patent. In line with current prevailing legal opinion and policy, very few thought that genes should be patentable. By contrast, views were divided almost 50-50 when it came to synthetic molecules (such as the Melbourne team's 'star peptide' or Oxford Jack Hoffman's 'BioBeads'). There was almost universal agreement that applications should be patentable (those who disagreed with this were generally those who appeared opposed to patenting in general and did not select any options). Patentability for computer code and algorithms also had widespread support.

WHICH OF THE FOLLOWING DO YOU BELIEVE SHOULD BE PATENTABLE?



The graph below shows that profit is the least important considerations to students, but all others ranked more or less equally overall. It seems the dismissal of maximising profit is limited to the context of companies profiting from ideas as ensuring the creators themselves are able to reap the rewards of their inventions was the a popular choice. The most important factor overall was benefit to society.

WHICH OF THE FOLLOWING DO YOU BELIEVE SHOULD BE A PRIORITY FOR POLICY MAKERS?



Recommendations...

To Politicians

Legislators have the difficult task of balancing a number of diverse and often conflicting intellectual property consideration. On the one hand, the government must incentivize innovation - IP is an essential means of achieving this, as demonstrated by studies showing how patents can positively influence innovation by a margin of 15-25%¹⁰. The flipside of this is the responsibility of the government to prevent the creation of monopoly and to ensure that ideas are shared so as to maximize productive research. Again, there is research indicating that intellectual property is crucial to maintaining this balance, as some studies have expressed concerns that patents on initial discoveries may 'delay, hamper, or deter' innovations building on the patented work. The transaction cost of working with patented material is unattractive to many researchers, particularly individuals and start-ups.

Based on our research and our experiences during iGEM and in the field of IP, we believe that one of the most important roles for the government is to lead a new, more imaginative line of thinking about intellectual property protection, and to move away from analyzing these issues within the traditional and deeply engrained innovation v access dichotomy.

Creating legal mechanisms to support this kind of innovative and flexible thinking about IP will be increasingly important to synthetic biology and to iGEM as the field grows increasingly complex and the dynamics between the many different interested parties continue to evolve. In order to successfully balance the demands of the public interest, investors, the environment, researchers, and inventors we will need to be more open minded when considering how to deal with IP in the future. It will not suffice to simply ask whether 'to patent or not to patent' and suppose that this is the extent of the available options.

A further issue which we believe needs addressing by a change in the law is the current incapacity of the law to provide protection for computer code and algorithms. This is an issue which extends far beyond iGEM. Counter-intuitively, the lack of protection for algorithms means that this information can justifiably be kept secret rather than being visible and accessible to the public and/or regulators. The danger of this situation was demonstrated only recently by Facebook's so called 'social experiment' during which the company controlled the newsfeed content of users in an attempt to manipulate their emotions. Jim Sheridan, a member of the Commons Media Select Committee, expressed his 'worries about the ability of Facebook and others to manipulate people's thoughts in politics or other areas', and stressed the need for legislation in this area.

One of the most interesting elements of our research into intellectual property is the situation in relation to computer code and models. We believe iGEM should consider extending its support to the growing campaign to create a form of IP protection for code and algorithms. Currently code is copyright but this is insufficient as it can be contravened legally by simply moving around the order of the terms within an equation. It is not currently possible to directly patent an algorithm. It is almost universally acknowledged amongst intellectual property lawyers that roundabout mechanisms for patenting algorithms are beginning to develop, but that these distort the law and are unreliable. Protection for computer code would allow engineers and mathematicians focussing on the modelling aspect of iGEM to follow a similar approach to that which has been so successful in the context of the biochemistry elements of iGEM. A balance between sharing of information and maintaining market viability could be struck.

Counter intuitively, it is entirely likely that making available some form of protection would encourage sharing of algorithms, especially by large and influential parties such as google and facebook whose algorithms wield immense social power. If there were a means of protecting these algorithms, companies could justifiably be compelled to open them to public scrutiny.

The issues involved are complex and nuanced, but in any case it is clear that iGEM has a stake in this rising debate and that it is worthwhile engaging with the issue. Whatever iGEM's position on this matter may be, the foundation views are significant as they are likely to be influential not just upon policy decisions but also upon the views of other parties.

To iGEM

The BioBrick agreements are currently not available on the iGEM page and many students reported having difficulties finding them – as these documents are so central to the iGEM competition, it may be worthwhile considering highlighting them on the competition homepage so that students can easily find this information about the legal contract they are making.

Confidentiality clause added into signup agreement so that the jamboree is no longer in the public domain. Teams then have discretion to apply for a patent for a limited period following the jamboree.

A further issue is the lack of accessible information for students making decisions about the ownership of intellectual property created during their project. Possible expansion of the guidance given in this document might help students to navigate this issue successfully and ensure their project and ideas realise their full potential in whatever way is best for them. Alternatively, iGEM could simply encourage teams to explore and research these issues for themselves – in many cases, we found that students were not confused so much as unconcerned about IP.

The indisputable conclusion is that iGEM's policy on intellectual property will shape the future of the competition. Given iGEM's influence in the field of synthetic biology, there is also great potential for this to impact on the future development of the field in key areas such as its investment and goals. For these reasons, this is an issue which should be given careful consideration.

To Students

Making the decision how to deal with intellectual property can be difficult and initially can feel overwhelming. With this in mind, we have developed a simple flow chart to aid the decision making process and highlight relevant factors. Ultimately, however, there is no magic formula which can give you the right solution – your decisions regarding IP rights are a value judgement, and you will see that many of the issues raised below imply issues of morality which you must determine for yourself.

How did this affect our own project?

Initially our team discussed whether a patent application to protect the intellectual property relating to our BioBeads would be the right path to go down. After a great deal of debate, we ultimately decided that we would prefer not to as we were excited by the possibility of other iGEM Projects using the beads, and felt this was more beneficial to the development of the concept than commercial investment.

For us, the determining factor was therefore the fifth question in our flow chart: is obtaining IP rights likely to attract commercial investment and so advance development of our idea. Although we felt that commercial investment would have been a possibility, the potential to find applications for the BioBeads within iGEM and other open source areas was overwhelming, especially given that little financial investment would be required to develop and manufacture the beads (they are made of biopolymer and agarose which is not prohibitively expensive).

The weight to be afforded to each stage in the decision making process is up to you, and will depend on what you want to achieve, who you want to help, and what your personal beliefs are on this issue. There are no right or wrong answers!



Should I file a patent application?

Is the **subject matter** patentable?

- The situation is currently unclear – the line between patentable and non-patentable material is blurry and varies between jurisdictions. You will likely have to do jurisdiction-specific research to determine the exact situation.
- As a general guideline, it appears that a DNA sequences itself may not be protected, but a specific function/application of that process may be.
- It is not currently possible to directly patent an algorithm (although it may be possible to obtain some protection through indirect means, for example by defining the algorithm in terms of a 'business method' or other patentable material)

Is your invention **novel, non-obvious, enabled in practice** (i.e. you are able to carry it out), and **useful**?

- The 'novelty' of your idea will be affected by any publication of information relating to it you have made – it is therefore important to maintain absolute confidentiality until you have filed your application. If publication cannot be avoided, check out the specific regulations in your jurisdiction – some regions such as the US allow a 'grace period' after release of information during which it may still be possible to file an application.

Are the rights to the idea **definitely yours**?

- Some institutions and most employers may have a claim to any work done during the courses of employment.

Will a patent be **value for money**?

- IP rights have, in the words of Bill Gates, 'the shelf-life of a banana'. Admittedly this is an exaggeration, but it is worth bearing in mind that the protection will not last forever.
- Further, patent applications can be prohibitively expensive – in the UK for example, even the initial process of filing an application for priority patent can cost several thousand pounds.
- It is therefore important to be realistic about whether the value of patent protection is worth the costs of procuring it.

Is obtaining IP rights likely to **encourage potential investors** and thereby **advance development** of your idea?

- Investors in your idea will want to be sure that their competitors cannot simply replicate their business model.

Is there a **compelling public interest** in placing your discovery in the public domain?

- In some instances, particularly for example in the context of medical research or fields with a similarly strong public interest element, you may wish to consider the ethical implications of creating a monopoly. This may well be taken into account implicitly or explicitly in the decision whether or not to grant your patent application.

Answered 'Yes' to everything? A patent application may well be the right decision

- If you have answered yes to all of the above questions, it may be in your interests to seek intellectual property rights to protect your idea.
- This guide is not intended to be exhaustive or conclusive advice. It is merely a suggestion as to the factors you may wish to take into account when deciding whether or not to file a patent. You should consult from a qualified legal professional before taking any firm decisions.

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⁷ Many thanks to the University of British Columbia 2012

(http://2012.igem.org/Team:British_Columbia/Human_Practices/IP_FAQ) and Calgary Entrepreneurial Team 2013

(http://2013.igem.org/Team:Calgary_Entrepreneurial/Project/IP/) for the assistance and inspiration we gained from reading about their work in human practices.

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With thanks to...

Oxford University iGEM team would like to express their gratitude for the help and advice of the following parties in the production of this document:

- ❖ The Morph Bioinformatics Team.
- ❖ Calgary Entrepreneurial Team 2013.
- ❖ University of British Columbia 2012.
- ❖ Dr Michael Morrison (STEMBANCC Researcher, HeLEX - Centre for Health, Law and Emerging Technologies; Nuffield Department of Population Health, University of Oxford).
- ❖ UCL iGEM Team for their organisation of the YSB event.
- ❖ Our sponsors for all their support!